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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,840	01/28/2002	Patrick Soon-Shiong	420042000200	7072
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MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			ANDERSON, JAMES D	
		ART UNIT	PAPER NUMBER	
		1614		
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/04/2007	PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/937,840	SOON-SHIONG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 December 2006.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 15-17,20-25 and 48-74 is/are pending in the application.
- 4a) Of the above claim(s) 49,53,63 and 67 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 15-17,20-25,48,50-52,54-62,64-66 and 68-74 is/are rejected.
- 7) Claim(s) 16 and 55 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                         |

**DETAILED ACTION**

Applicants' arguments, filed 12/21/2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. Upon further consideration, the following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The indication of allowable subject matter in the Office Action mailed 8/23/2006 is hereby withdrawn.

In light of the new rejections being applied against the instant claims, this Office Action is Non-Final.

*Status of the Claims*

Claims 15-17, 20-25 and 48-74 are currently pending and are the subject of this Office Action. Claims 48-74 are newly presented. Claims 49, 53, 63 and 67 are withdrawn from consideration. Claims 15-17, 20-25, 48, 50-52, 54-62, 64-66 and 68-74 are presently under examination.

*Election/Restrictions*

Claims 49, 53, 63 and 67 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking

claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/22/2004.

The Requirement for Restriction/Election mailed on 12/22/3003 required the election of a species of active agent. In response, Applicants elected “chemotherapeutic agents”. The previous Examiner maintained the Restriction Requirement in the Office Action mailed 5/26/2004. Claims 49, 53, 63 and 67 recite antibiotics and immunosuppressive agents as the pharmacologically active agent of the instantly claimed compositions. As such, the claims are drawn to a non-elected species and are withdrawn from consideration. It is clear from the Markush group recited in instant claim 16 that chemotherapeutic agents, antibiotics and immunosuppressive agents are distinct species of active agents.

#### *Claim Objections*

Claims 16 and 55 are objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 15, from which claims 16 and 55 ultimately depend, recites a unit dosage form of a pharmacologically active agent effective against cancer. However, claims 16 and 55 recite agents that are not generally effective against cancer (*e.g.* antibiotics, anesthetics, antiinfectives, antidepressants, etc.).

Claim 16 is objected to because of the following informalities: “antiinfectives” is recited twice in the claim (line 5 and lines 12-13). Appropriate correction is required.

***Claim Rejections - 35 USC § 112 (1<sup>st</sup> Paragraph)***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-17, 20-22, 25, 48, 50-52, 54-59, 62 and 64-74 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The claims are drawn to unit dosage forms comprising a "pharmacologically active agent". The specification discloses examples of pharmacologically active agents (e.g., pages 10-16), which include chemotherapeutic agents, taxanes, epitholones, agents which modify microtubule activity or assembly, small molecule drugs, biologics, peptides, antibodies, enzymes, antisense therapeutics, polynucleotides and many other general classes of pharmacologically active agents. The specification exemplifies the drug paclitaxel (pages 2-3 and Example I, pages 18-19). The claims, in their broadest reasonable interpretation read on a dosage form comprising any compound.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or

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chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is a recitation of broad classes of active agents, which encompass compounds with varying structures, activities, and pharmacological profiles. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genera.

The claims are further drawn to multiple genera of compounds that are defined only by biological activity (*e.g.* chemotherapeutic drugs, agents which modify microtubule activity or assembly, antiinfectives, antirejection drugs, antimanic agents, antiparkinson agents, etc.). Other genera are drawn to compounds with no defining characteristics (*e.g.* taxanes, epitholones, small molecule drugs, biologics, peptides, antibodies, enzymes, polynucleotides, etc.). Claim 15 recites “a pharmacologically active agent” but does not define any structural features of said agent.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of the complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present is that a particular active agent has some kind of biological activity. In many cases, no biological activity is recited and no structural features are defined. In the case of agents with a defined biological activity, there is no description of structural characteristics that are required to retain

biological activity. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genera, aside from the specific agents recited in the Specification. The recited genera of active agents are so broad that the claims effectively read on any and all biological and chemical compounds.

*Vas-Cath, Inc. v. Mahurkar*, 19USPQ2d 111, clearly states, “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed *supra*, the skilled artisan cannot envision the detailed chemical structure of the encompassed genera of active agents (other than those explicitly named in the Disclosure), and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or synthesis. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or synthesizing it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only those active agents specifically named in the specification, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes it clear that the written description

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provision of 35 U.S.C. § 112 is severable from its enablement provision (see *Vas-Cath* at page 1115). See also *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement).

Claims 16, 22, 50-52, 55, 59 and 64-66 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

In the instant case, the rejected claims recite broad genera of active agents with no identifying structural characteristics (e.g. taxanes, derivatives, small molecule drugs, biologics, antibiotics, antineoplastics, etc.)

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

While the specification describes a few species of instantly claimed active agents, it does not describe a sufficient number of species as to convey possession of the entire genera encompassed by the instant claims. For example, other than paclitaxel and taxotere, the agents encompassed by “taxane” and “derivatives” are not defined by any particular structural characteristics.

***Claim Rejections - 35 USC § 112 (2<sup>nd</sup> Paragraph)***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-17, 20-25, 48, 50-52, 54-62, 64-66 and 68-74 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, the claims recite the limitation “1% up to about 20% of the conventionally administered amount”. This limitation is indefinite because the conventionally administered amount of any particular pharmacologically active agent depends on multiple factors, including the drug, metabolism, pharmacokinetics, the patient’s weight, age and general health and the condition being treated. As such, claims drawn to a unit dosage form of a pharmacologically active agent comprising about 1% up to about 20% of the conventionally administered amount of said agent are indefinite because the metes and bounds of the patent protection sought are not clear. One skilled in the art would not know exactly what doses are encompassed by the claims (e.g. 1 mg, 10 mg, etc.). Further, pharmacologically active agents are often administered in single doses, multiple doses

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and continuous doses. It is not clear if the “conventionally administered amount” refers to a single dose (*e.g.* 10 mg injection), a multiple dose (*e.g.* 10 mg injection every 4 hours) or a continuous dose (*e.g.* 20 mg/m<sup>2</sup>/hour continuous *i.v.*). As such, it is impossible to determine exactly how much active agent will be present in the instantly claimed compositions.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-17, 20-23, 25, 48, 50-52, 55-60, 62 and 64-66 are rejected under 35 U.S.C. § 102(a) as being anticipated by Isokangas *et al.* (Lung Cancer, 1998, vol. 20, pages 127-133) in view of Desai *et al.* (U.S. Patent No. 6,096,331; Issued Aug. 1, 2000; Filed Sep. 9, 1997).<sup>1</sup>

The instant claims recite unit dosage forms comprising a “sub-therapeutic dose level” of a pharmacologically active agent, wherein the dose comprises “about 1% up to about 20% of the conventionally administered amount” of said active agent (see especially claim 15). Desai *et al.*

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<sup>1</sup> Desai *et al.* is cited to show that a “conventionally administered” dose of paclitaxel was known in the art to be about 135 to 200 mg/m<sup>2</sup>.

teach that “therapeutically effective doses” of paclitaxel typically fall in the range of 135 mg/m<sup>2</sup> to 200 mg/m<sup>2</sup>, with doses of 175 and 200 mg/m<sup>2</sup> being preferred (col. 13, lines 7-11)

Isokangas *et al.* teach a method of treating inoperable stage III non-small cell lung cancer (NSCLC) comprising administering paclitaxel and carboplatin in combination with radiotherapy (Abstract). Following an induction dose of 135 mg/m<sup>2</sup> (a therapeutic dose) of paclitaxel, paclitaxel was subsequently administered at a dose of 30 mg/m<sup>2</sup> over 1 hour (administered via infusion), given 2-4 hours prior to irradiation (page 128). This dose is about 20% of 135 mg/m<sup>2</sup>, 17% of 175 mg/m<sup>2</sup> and 15% of 200 mg/m<sup>2</sup> conventionally administered paclitaxel. The reference thus teaches administration of a composition comprising a sub-therapeutic dose of paclitaxel.

Claims 15-17, 20-22, 24-25, 48, 50-52, 55-59, 61-62 and 64-66 rejected under 35 U.S.C. § 102(b) as being anticipated by Pazdur *et al.* (J. Natl. Cancer Inst., 1992, vol. 84, pages 1781-1788) in view of Burstein *et al.* (Journal of Clinical Oncology, 2000, vol. 18, pages 1212-1219).<sup>2</sup>

The instant claims recite unit dosage forms comprising a “sub-therapeutic dose level” of a pharmacologically active agent, wherein the dose comprises “about 1% up to about 20% of the conventionally administered amount” of said active agent (see especially claim 15). Burstein *et al.* teach that docetaxel in the treatment of breast cancer is administered in a dose of 75 to 100 mg/m<sup>2</sup> as a 1-hour infusion every 21 days (*i.e.* conventional dose).

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<sup>2</sup> Burstein *et al.* is cited to show that a “conventionally administered” dose of docetaxel was known in the art to be about 75 to 100 mg/m<sup>2</sup> as a 1-hour *i.v.* infusion every 21 days.

Pazdur *et al.* administered taxotere (*i.e.* docetaxel) as a 1-hour infusion at a starting dose of 1 mg/m<sup>2</sup> per day for 5 consecutive days (*i.e.* total cumulative dose of 5 mg/m<sup>2</sup>) every 21 days. This dose equates to about 5% (of 100 mg/m<sup>2</sup>) or about 7% (of 75 mg/m<sup>2</sup>) of the conventionally administered dose of docetaxel. It is taught that docetaxel was provided as a concentrated 1-mL or a 5-mL sterile solution comprising 15 mg/mL docetaxel (page 1782). This solution was diluted to a final concentration of 0.3 mg/mL (*id.*) and administered to patients via infusion. The reference thus teaches dosage forms comprising 5% to about 7% of the conventionally administered dose of docetaxel.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 54 and 68 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pazdur *et al.* as applied to claims 15-17, 20-22, 24-25, 48, 50-52, 55-59, 61-62 and 64-66 above and in further view of WO 98/53811 (Published December 3, 1998).

Pazdur *et al.* disclose as discussed *supra*. In summary, Pazdur *et al.* administered taxotere (*i.e.* docetaxel) as a 1-hour infusion at a starting dose of 1 mg/m<sup>2</sup> per day for 5 consecutive days (*i.e.* total cumulative dose of 5 mg/m<sup>2</sup>) every 21 days. The reference does not disclose oral administration of docetaxel.

However, WO '811 discloses oral administration of taxanes for the treatment of cancer (Abstract; page 9, lines 8-10; page 17, lines 13-14).

Thus, it would have been *prima facie* obvious to formulate compositions comprising taxanes that could be administered orally. It is noted that oral administration of chemotherapeutic agents is well known in the art. As such, if a dosage form is known in the art, it is generally obvious to administer such a dosage form by any suitable means, including orally. In this case, although taxanes are traditionally administered *via* infusion, WO '811 provides one skilled in the art with the means and motivation to orally administer dosage forms comprising taxanes.

Claims 69-74 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Isokangas *et al.* as applied to claims 15-17, 20-23, 25, 48, 50-52, 55-60, 62 and 64-66 above, and further in view of Lambert *et al.* (U.S. Patent No. 6,458,373; Issued Oct. 1, 2002; Filed Jan. 5, 1998).

Isokangas *et al.* disclose as discussed *supra*. In summary, the reference discloses administration of 30 mg/m<sup>2</sup> paclitaxel by infusion. The reference does not disclose a composition encapsulated in a colloidal dispersion system.

However, Lambert *et al.* disclose emulsions comprising α-tocopherol and therapeutic drugs (Abstract). The therapeutic drug can be paclitaxel, as exemplified in the Examples (columns 10-15).

Examiner notes that the instantly claimed microspheres and oil-in-water emulsions are well known in the art, as evidenced by Lambert *et al.*, as delivery methods for therapeutic agents. As such, it would have been *prima facie* obvious to formulate a composition comprising paclitaxel in an emulsion vehicle.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent No. 6,753,006

Claims 15-17, 20-25, 48, 50-52, 55-62 and 64-66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 7, 10-11 and 14 of U.S. Patent No. 6,753,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '006 patent recite unit dosage forms of paclitaxel comprising a sealed vial containing "a quantity" of paclitaxel wherein said quantity is sufficient to deliver a dose of 30-1,000 mg/m<sup>2</sup> over an administration period. As discussed *supra*, 30 mg/m<sup>2</sup> would be considered by those skilled in the art to be a sub-therapeutic dose of paclitaxel. As such, the instant claims recite compositions which encompass the subject matter claimed in the compositions of the '006 patent.

U.S. Patent No. 6,096,331

Claims 15-17, 20-25, 48, 50-52, 55-62 and 64-66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 31-33, 36, 39, 48 and 51 of U.S. Patent No. 6,096,331. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '331 patent recite formulations comprising taxanes in dose ranges of 30-1,000 mg/m<sup>2</sup>. As discussed *supra*, 30

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mg/m<sup>2</sup> would be considered by those skilled in the art to be a sub-therapeutic dose of a taxane.

As such, the instant claims recite compositions which encompass the subject matter claimed in the compositions of the '331 patent.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James D. Anderson, Ph.D.  
Patent Examiner

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March 27, 2007

Phyllis Spivack  
PHYLLIS SPIVACK  
PRIMARY EXAMINER  
3/29/07